



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,686	06/15/2007	Peter Rauch	FLGDK32.001APC	2841

20995 7590 09/15/2009
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

HAQ, SHAFIQUL

ART UNIT	PAPER NUMBER
----------	--------------

1641

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

09/15/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/590,686	Applicant(s) RAUCH ET AL.	
	Examiner SHAFIQL HAQ	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/15/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Election-Restriction

1. Applicants' election of a single species for "compound A", "a non-ionic detergent", "binding pair" and "buffer", filed June 25, 2009 in response to Office Action of May 28, 2008 is acknowledged and entered. Applicants have elected "ethylene glycol" for a single species of "compound A", "poly(oxyethylene) (20) sorbinate monolaurate (Tween 20)" for a single species of "a non-ionic detergent", "antigen-antibody binding pair" of a single species of "binding pair" and "phosphate buffer" for a single species of "Buffer" is acknowledged.

Because applicant did not traverse election requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, the restriction requirement is deemed proper and is made FINAL.

2. Claims 28-49 are examined on merits in this office action to the extent they encompasses the elected species.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 28-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occurs.

Art Unit: 1641

6. Claim 1 recites the term "unspecific binding" in line 1 and claim 29 recites "non-specific antibody binding" in line 2. Specification of instant application does not define the terms "unspecific" and "non-specific" and thus it is unclear how is the term "unspecific" different from the term "non-specific". Further, claims 28 and 43 recite the term "disturbing effects of matrices" in line 2 for which there is clear description or definition in the specification and thus it is unclear what effect(s) of matrices Applicants are intended to encompass by the term "disturbing effects of matrices".
7. In claim 37, the valency of the carbon attached to OH group in the substitution group "-[O-CH₂-CH₃]-OH in the compound shown in paragraph b) is incorrect.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 28, 32, 34-39, 41-43 and 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Salomen (GB 2062224A).

Salomen discloses an immunoassay method wherein the immunoassay method comprises reaction of the binding pair member in a solution comprising phosphate buffer, polyethylene glycol (i.e. compound A), a non-ionic detergent (e.g. Tween 20), and NaCl (See Examples 1 and 3). Serum samples and antibodies against the analyte are diluted in this buffer. The composition in the reaction mixture being

Art Unit: 1641

comprising the same reaction components would inherently reduce unspecific binding reaction of the binding pair.

Therefore, the reference is deemed to anticipate claim 28.

With regard to claim 32, as described above, the reaction mixture comprises NaCl.

With regard to claims 34 and 35, as described above, the reaction mixture comprises phosphate buffer and polyethylene glycol.

With regard to claim 36, Salomen discloses 4% and 3% polyethylene glycol (See Examples 1 and 3), which falls within the range of 0.5 to 25% and thus the claim is anticipated.

With regard to claim 37, Salomen teaches Tween 20 in the reaction mixture and Tween 20 reads on the compound of claim 37.

With regard to claim 38, as described above, Salomen teaches Tween 20.

With regard to claim 39, Salomen teaches 0.1% Tween 20, which anticipates claim 39 as the value (0.1%) falls within the range of 0.1 to 1.0%.

With regard to claim 41, the reaction mixture of Salomen does not contain dithiothreitol.

With regard to claim 42, Salomen discloses that the pH of phosphate buffer is 7.2 and the pH reads on the adjusted pH value of 5.6-9.6.

With regard to claim 43, as described above, the composition in the reaction mixture being comprising the same reaction components would inherently have the capability of reducing unspecific binding reaction of the binding pair.

Art Unit: 1641

With regard to claim 47, the composition being capable of unspecific binding reaction would inherently increase the binding activity of affinity of antibodies.

With regard to claim 48, Salomen teaches antibody antigen binding pair.

10. Claims 28, 32, 34-38, 42-43 and 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Figard (US 5,616,460).

With regard to claim 28, Figard discloses aqueous composition suitable for use as a buffer in immunoassay method involving binding of specific binding pairs (e.g. antibody-antigen binding) and the composition comprises a biological buffer to control pH and ethylene glycol (i.e. compound A) (Abstract; column 2, lines 40-67 and column 3, lines 31-32). Figard teaches that the composition can also include at least one biological detergent, at least one source of positive and negative counterions, e.g. salt, and at least one viscosity modifier, e.g. sugar (column 2, lines 44-47 and column 5, lines 1-5). Figard teaches that the composition reduces non-specific binding, which includes non-ionic detergents (column 5, lines 6-35).

Therefore, the reference is deemed to anticipate independent claim 28.

With regard to claim 32, as described above, the reaction mixture may comprise suitable source of positive and negative counterions (column 2, lines 44-47), as for example NaCl (column 5, lines 65-68).

With regard to claims 34 and 35, as described above, the reaction mixture comprises biological buffer and ethylene glycol, and the biological buffer includes MES, HEPES and PIPES (column 3, line 30 to column 4, line 19).

Art Unit: 1641

With regard to claim 36, Figard discloses 4-5% ethylene glycol (Column 6, lines 25-34), which is within the range of 0.5 to 25% and thus the claim is anticipated.

With regard to claims 37 and 38, Figard teaches Tween 20 as biological detergent and Tween 20 reads on the compound of claim 37 (column 5, line 20).

With regard to claim 42, Figard discloses preferred pH of the composition is 6.6 (column 2, line 52) and the pH reads on the adjusted pH value of 5.6-9.6.

With regard to claim 43, as described above, the composition is capable of reducing unspecific binding reaction of the binding pair (column 5, lines 6-15 and 36-38).

With regard to claim 47, the composition being capable of unspecific binding reaction would inherently increase the binding activity of affinity of antibodies.

With regard to claim 48, Figard teaches antibody antigen binding pair (column 1, lines 6-9).

11. Claims 28, 29, 30, 32, 34-38, 41-43 and 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Siedel *et al* (US 4,485,177).

With regard to claim 28, Siedel teaches a reagent suitable for use in an immunoassay method involving binding of specific binding pairs (e.g. antibody-antigen binding) and the reagent comprises a buffer to control pH (e.g. phosphate buffer), Tween 20 non-ionic detergent and a salt (e.g. NaCl) (see example 2, lines 25-47 of column 10). The reagent preferably also contains a substance wherein the substance is polyethylene glycol (column 6, lines 41-49). Figard teaches that the composition reduces non-specific binding, which includes non-ionic detergents

Art Unit: 1641

(column 5, lines 6-35). The composition in the reaction mixture being comprising the same reaction components would inherently reduce unspecific binding reaction of the binding pair.

Therefore, the reference is deemed to anticipate independent claim 28.

With regard to claims 29 and 30, Siedel teaches that turbidimetric immunoassay further comprising BSA (column 6, lines 53-61).

With regard to claim 32 Siedel discloses the reaction mixture comprising NaCl (column 10, line 35).).

With regard to claims 34 and 35, as described above, the reaction mixture comprises phosphate buffer (column 10, line 25-46).

With regard to claim 36, Siedel discloses 0.1-8% polyethylene glycol (Column 6, lines 59-60), which has substantial overlapping with the concentration range of compound A of claim 36 and thus the claim is anticipated.

With regard to claims 37 and 38, Siedel teaches Tween 20 and Tween 20 reads on the compound of claim 37 (column 5, line 20).

With regard to claim 41, the reaction mixture of Siedel does not contain dithiothreitol.

With regard to claim 42, Siedel discloses pH 7.2 of the composition (column 10, line 33) and the pH anticipates the adjusted pH value of 5.6-9.6.

With regard to claim 43, as described above, The composition in the reaction mixture being comprising the same reaction components would inherently reduce unspecific binding reaction of the binding pair.

Art Unit: 1641

With regard to claim 47, the composition being capable of unspecific binding reaction would inherently increase the binding activity of affinity of antibodies.

With regard to claim 48, Siedel teaches antibody antigen binding pair (column 2, lines 41-46 and Abstract).

12. Claims 28-38, 41-43 and 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart (US 6,503,702 B1).

With regard to claim 28, Stewart teaches immunoassay buffer system comprising a buffer to control pH (e.g. sodium carbonate, sodium borate or Tris-saline), a detergent, a salt, a stabilizing agent and a protein which is not recognized by any of the antibodies used in the assay (column 5, lines 48-55). The stabilizing agent can be polyethylene glycol, glycerol or ethylene glycol (column 6, lines 54-57), which reads on compound A of instant claim 28. The composition in the reaction mixture being comprising the same reaction components would inherently reduce unspecific binding reaction of the binding pair.

Therefore, the reference is deemed to anticipate independent claim 28.

With regard to claims 29, 30 and 31, Stewart teaches that the protein which is not recognized by any of the antibodies may be selected from BSA, ovalbumin, casein and fetal bovine serum at a concentration range of 0.1-2% (column 7, lines 25-40).

With regard to claims 32 and 33 Stewart teaches that the salt may be selected from NaCl and potassium chloride and the concentration of 140mM, which anticipates 100mM to 1.5M of claim 33 of instant application (column 6, lines 23-31).

Art Unit: 1641

With regard to claims 34, Stewart teaches the buffer can be Tris-saline buffer (column 5, lines 64-65), which reads on Tris (Tris(hydroxymethyl)-aminomethane buffer of instant claim 34.

With regard to claims 35, Stewart teaches that the stabilizing agent can be polyethylene glycol, glycerol or ethylene glycol (column 6, lines 54-57).

With regard to claim 36, Stewart teaches polyethylene glycol at 1% (column 6, line 59-60), which is within the concentration range of compound A of claim 36 and thus the claim is anticipated.

With regard to claims 37 and 38, Stewart teaches that the detergent can be Tween 20 and Tween 20 reads on the compound of claims 37 and 38 (column 6, line 17).

With regard to claim 41, the reaction system of Stewart does not contain dithiothreitol.

With regard to claim 42, Stewart discloses pH between 7.5-8.5 of the buffer system (column 5, line 61) which lie within the range of 5.6-9.6 of instant claim 42 and thus the pH of the buffer system of Stewart anticipates the adjusted pH value of claim 42.

With regard to claim 43, as described above, the composition in the reaction mixture being comprising the same reaction components would inherently reduce unspecific binding reaction of the binding pair.

With regard to claim 47, the composition being capable of unspecific binding reaction would inherently increase the binding activity of affinity of antibodies.

Art Unit: 1641

With regard to claim 48, Stewart teaches antibody antigen binding pair (column 3, lines 35-63 and column 4, lines 24-37).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 33, 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salomen (GB 2062224A).

See the above teaching of Salomen for reaction composition of an immunoassay. Salomen discloses different concentration of the components in the reaction buffer composition but however, does not disclose ratio of non-ionic detergent to polyethylene glycol, ionic strength.

Salomen discloses 3% PEG and) 1% Tween, i.e. a ratio of 1:30 (see example 3). However, the adjustment of particular working conditions (such as ionic strength, ration of different reaction components) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a).

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the .general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d

Art Unit: 1641

454,456, 105 USPQ 233,235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 .("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)

With regard to claim 49, the substitution of the antibody-antigen binding pair with other binding pair such as receptor-ligand binding pair, as claimed, is considered to be an obvious variation for detection of different analyte, i.e. one of ordinary skill in the art would expect such a substitution of one binding pair with another to result in an equivalently useful immunoassay for detection of different analytes

15.. Claims 33, 39, 40, 44-46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Figard (US 5,616,460).

See the above teaching of Figard for composition of an aqueous solution for an immunoassay. Figard discloses different concentration of the components in the reaction buffer composition, but however, does not mention ratio of non-ionic detergent to ethylene glycol and ionic strength of the aqueous solution.

However, the adjustment of particular working conditions (such as ionic strength, ration of different reaction components) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a) absent unexpected results.

Art Unit: 1641

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the .general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 .("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)

With regard to claim 49, the substitution of the antibody-antigen binding pair with other binding pair such as receptor-ligand binding pair, as claimed, is considered to be an obvious variation for detection of different analyte, i.e. one of ordinary skill in the art would expect such a substitution of one binding pair with another to result in an equivalently useful immunoassay for detection of different analytes.

16. Claims 31, 33, 39, 40, 44-46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siedel *et al* (US 4,485,177).

See the above teaching of Siedel for an immunoassay composition. Figard discloses different concentration of the components in the reaction buffer composition, but however, does not mention ratio of non-ionic detergent to ethylene glycol and the range of ionic strength of the aqueous solution.

Siedel teaches different concentrations of buffer, PEG, albumin and a range of ionic strength of the buffer (column 6, lines 37-61 and column 7, lines 1-5). However,

Art Unit: 1641

the adjustment of particular working conditions (such as ionic strength, ratio of different reaction components) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a) absent unexpected results.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 .("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)

With regard to claim 49, the substitution of antibody-antigen binding pair with other binding pair such as receptor-ligand binding pair, as claimed, is considered to be an obvious variation for detection of different analyte, i.e. one of ordinary skill in the art would expect such a substitution of one binding pair with another to result in an equivalently useful immunoassay for detection of different analytes.

17. Claims 39-40, 44-46 and 49 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Stewart (US 6,503,702 B1).

See the above teaching of Stewart for an immunoassay buffer system. Stewart discloses different concentration of the components in buffer system, but however,

Art Unit: 1641

does not mention ratio of non-ionic detergent to ethylene glycol and does not disclose the range of concentration of non-ionic detergent as claimed.

Siedel teaches different concentrations of buffer, stabilizing agent, salts, detergents and non-specific proteins (column 5, line 48 to column 7, line 40). Stewart teaches different concentrations of non-ionic detergent and teaches that the concentration must be carefully chosen so that the dissolution of cellular material is balanced against the denaturing effects of the detergent (column 6, lines 6-11). The composition of the buffer system also being comprising the same composition of instant claim 28, would be capable of preventing low affinity binding and one of ordinary skill in the art can easily optimize different concentrations of the components of the buffer system to find an optimum K_D value for low-affinity binding with the expectation of increasing detection sensitivity, with a reasonable expectation of success. Further, the adjustment of particular working conditions (such as ionic strength, ratio of different reaction components) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan and therefore obvious under 35 U.S.C. § 103(a) absent unexpected results.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the .general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65

Art Unit: 1641

USPQ2d at 1382 .("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.)

With regard to claim 49, the substitution of antibody-antigen binding pair with other binding pair such as receptor-ligand binding pair, as claimed, is considered to be an obvious variation for detection of different analyte, i.e. one of ordinary skill in the art would expect such a substitution of one binding pair with another to result in an equivalently useful immunoassay for detection of different analytes.

Conclusion

18.No claims are allowed.

19.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Primary Examiner, Art Unit 1641